

[0081] FIG. 24 shows graphed experimental results of a total PSA half dried 2 step assay performed with reagents dried in the MST Pro Strip V1 and the assay performed on the MST Pro Meter V1. In this case the magnetic particles were deposited in the test cartridge in dry format;

[0082] FIG. 25 shows graphed experimental results of a scan across a test sample channel in the strip MST Pro Strip V1 using the instrument MST Pro Meter V1; and

[0083] FIG. 26 shows a schematic representation of further embodiments of a sample cartridge (MST pro strip V1, as used in the experimental section) in accordance with the present invention.

[0084] A sample cartridge (10) in accordance with an embodiment of the present invention is shown in FIG. 1. A fluid such as blood is applied to the sample introduction port (12) (via, for example, finger or venous blood). In this particular embodiment two channels (14,16) span from this one sample introduction port (12), the channels (14,16) are separate and are not joined, although to the user who is applying the blood the channel may appear as one. Although not to be construed as limiting, the further description will relate to the sample being a sample of whole blood.

[0085] The total sample application may be smaller than 1  $\mu$ L depending on the number of channels to fill therefore when the user applies a sample, such as a drop of blood, both channels (14,16) will fill under capillary force. This process is very fast and more in tune with blood glucose strip filling as opposed to the lengthy blood separation filling of some immunoassay platforms. Deposited in the two channels (14, 16) are magnetic particles functionalised with antibody (18). As will be described in more detail, the blood fills each channel (14, 16) to the fluidic stop features (20, 22), one stop (22) downstream of a sink void (28) and the other stop (20) in the main sample channel. Fluidic stop features may be created by applying a printable hydrophobic ink to a surface of the channel. When the cartridge (10) is formed from three substrates (50, 52, and 54) as shown in FIG. 2b, the hydrophobic ink may be applied to top (50) and bottom (54) substrates, so as to form a stop feature on the top and bottom surfaces of a channel. The fluidic stop features (20, 22) in the main sample channel may also act as fill detect electrodes if made of a suitable hydrophobic electrically conductive material. As the cartridge (10) is inserted into the reader, a cartridge heating mechanism may be initiated, heating the cartridge to a pre-defined constant temperature for the duration of the test. This allows many benefits which are commented on hereinafter.

[0086] At the end of each of the 2 sample channels (14, 16) on the cartridge there may be an electrode (23), see FIG. 2. There may also be an electrode (23) present near the overflow sink (28) (which could also be used as electrochemical measurement zones). Through the reader, checking the electrical continuity between the electrodes, the reader will be able to confirm that the channels (14, 16) have been successfully filled with sample. This can be performed through a simple conductance measurement. For a specific channel, if the electrodes (23) have been successfully wetted with blood (meaning that both channels have been filled completely with sample) then an electrical current can conduct from one electrode to the other through the blood sample. Otherwise if the blood sample is not present, or has only partially filled the channel, then one of the electrodes will not be wetted, meaning the electrical current cannot flow from one electrode to another.

[0087] In the present cartridge/assay system, it shall be possible to measure the hematocrit of the blood sample. The design of the cartridge means that the measurement can be performed without any interference from the reagents that are used for the primary assay functionality.

[0088] FIG. 3 shows a portion of the cartridge (1) in more detail and in particular the fluid stop features (20, 22). An additional feature (60) is shown adjacent to the sample application point (12). This feature (60) is designed to prevent any sample from wetting the outer surface of the cartridge upon sample application

[0089] The hydrophobic stop features (20, 22) are present on both inner surfaces removing any hydrophilic path resulting in the fluid stopping at this feature. In one embodiment two hydrophilic surfaces are utilised however alternative combinations of hydrophilic/hydrophobic surfaces could be used to fill the strip by capillary action. In an extreme example of this two hydrophobic inner surfaces could be utilised and by providing a "sucking" action by way of a pump in the reader the cartridge may be filled with the sample.

[0090] As the blood fills the sample channels (14, 16) (see FIGS. 4 and 5) the antibody functionalised magnetic particles (18) (which are pre deposited in the channel as dry reagents) are resuspended by the blood, thereby allowing binding any analyte/s present. The blood fills to the stop features (20, 22), see FIG. 5. Once the particles (18) are resuspended, incubation with the blood sample would be allowed to occur for a defined period of time (incubation time) and controlled by appropriate software and programming of the reader. Magnetic particles may be chosen as the capture phase due to their high mobility and functionality (size dependent i.e. diffusion coefficients etc) to reduce diffusion distances and ultimately incubation time. This type of reaction will be very efficient and reproducible at binding analyte from blood samples. During the magnetic particle binding of analyte, a hematocrit measurement may be performed by hematocrit electrodes (24). The hematocrit value can be used by the reader to calculate the final concentration of the analyte as the reference value will be a plasma measurement made by a clinical analyser. A hematocrit measurement may be required to correct for the concentration difference associated with analyte present in a given volume of sample due to differing ratios of red blood cells to plasma. Therefore a whole blood measurement may be corrected for this difference by means of a hematocrit measurement so that results are consistent with those associated with a plasma sample.

[0091] After the antibody functionalized magnetic particles (18) have bound any analyte in the blood a permanent magnet (80) or electromagnetic field is used to hold the analyte-antibody magnetic particle complex in place (see FIG. 6). A wash buffer or gas is then delivered from an inlet port (26). The wash medium is provided from a buffer reservoir/reservoirs present in the reader (a particular buffer reservoir/reservoirs and hence buffer may be inserted into the reader depending on the particular assay and hence analyte being detected). A defined volume of buffer (e.g. 1-2  $\mu$ L) is expelled from the reservoir/reservoirs of the reader via a pump system into the sample channels (14,16) pushing the blood past the fluid stop feature (22) into the sink void (28), leaving the magnetic particles in buffer. (See FIGS. 7 and 8). The magnetic particles (18) can be visualised as a discreet band (82) still held within the channel (14, 16).

[0092] After this step a series of further wash steps, as above, may be performed (all using the magnetic particle